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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,777	11/26/2003	Robert J. Marshall	PRL-101	7232
42419	7590	10/10/2006		
PAULEY PETERSEN & ERICKSON 2800 WEST HIGGINS ROAD SUITE 365 HOFFMAN ESTATES, IL 60195			EXAMINER UNDERDAHL, THANE E	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/722,777

Applicant(s)

MARSHALL, ROBERT J.

Examiner

Thane Underdahl

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-22 is/are pending in the application.
- 4a) Of the above claim(s) 13-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-12 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/04/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction Requirement

Applicant's election without traverse of Group II claims 4-12 in the reply filed on 8/30/2006 is acknowledged.

Election of Species

Applicant's species election with traverse of *Bifidobacterium* and *B. Longum* in the reply filed on 8/30/2006 is acknowledged. The election of species is withdrawn in light of the applicant's arguments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 12 teach "aboutcomposition weight percent". This is indefinite since the claim does not define a reference to the weight percent. In other words the applicant fails to provide an absolute standard to gauge the percent ratio. As written the claim could be drawn to the total weight of the composition or the weight of that component of the composition. Clarification is required.

Also claim 12 is indefinite since it teach "aboutcomposition weight percent of a paste". The specification does not clearly define the composition of the paste or what is its contribution of the total weight of the composition. Clarification is required.

Art Unit: 1651

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 depends on claim 4 which is a composition. However, claim 20 limits that the "prebiotic organism produces a stabilized dihydrolipoic acid". This appears to be a method step and does not add a component to further limit the composition. Clarification is required. In the interest of compact prosecution the examiner will interpret the claim as "The culture media of claim 4 comprising at least one probiotic organism for use in a medicament or a nutritional supplement".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-10 and 20-22 rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings et al. (U.S. Patent # 6,368,617) in view of Hermann et al. (European Journal of Pharmaceutical Sciences, 1996).

These claims 4-10 are drawn to a composition comprising three parts a) at least one live probiotic organism, R-Lipoic acid, and at least one nutritive agent. The probiotic organism can be from *Lactobacillus*, *Bifidobacterium*, *Enterococcus*, *Streptococcus thermophilus*. More specifically the microorganisms can be selected from the group consisting of: *L. acidophilus*, *L. paracasei*, *L. fermentum*, *L. rhamnosus*, *L. johnsonii*, *L.*

Art Unit: 1651

plantarum, *L. reuteri*, *L. salivarius*, *L. brevis*, *L. bulgaricus*, *L. helveticus*, *L. grasseri*, *L. casei*, *L. lactis*, *B. bifidum*, *B. breve*, *B. infantis*, *B. longum*, *B. lactis*, *E. faecium*, and *E. faecalis*.

Claim 21 is an additional composition comprising *B. longum*, *L. acidophilus*, *E. faecium*, *Streptococcus thermophilus* and R-Lipoic acid, and at least one nutritive agent. Claim 22 depends from claim 21 and further comprises *B. breve*, *B. infantis*, *L. casei*, *L. fermentum*, *L. helveticus*, and *L. plantarum*.

Claim 20 depends from claim 4 and further limits that the probiotic organism for use in a medicament or a nutritional supplement.

Hastings et al. teach a composition in claim 11 (col 7) comprising a probiotic blend of *B. bifidum* and *L. acidophilus*, a nutrient substance such as omega-3 fatty acids and saccharides, and can further comprise alpha-lipoic acid (claim 15, col 8). While Hastings does not teach solely the (R) enantiomer of lipoic acid it is obvious to use this enantiomer from the teachings of Hermann et al.

Herman et al. teach that of the racemic forms of alpha lipoic acid, the (R) enantiomer has greater bioavailability than the (S) enantiomer (Abstract, last 3 lines). One of ordinary skill in the art that knew of the teachings of Hermann et al. would recognize using the enantiomerically pure (R) form of lipoic acid would improve the composition of Hastings et al. The motivation is provided by Hastings et al. who show that the bioavailability of R-lipoic acid is superior to S-lipoic acid. The reasonable expectation of success is provided by Hastings et al. who show that the composition which already includes R-lipoic in a racemic mix with S-lipoic acid can be formulated.

Art Unit: 1651

Hastings et al. also does not teach a composition containing all the bacteria listed in claims 21 or 22. However these bacteria are well known in the art as probiotic bacteria as supported by Mercenier et al. (Current Pharm. Design Jan. 2003) and Dunne et al. (Antonie van Leeuwenhoek, 1999). Hastings et al. already uses a probiotic blend of *B. bifidum* and *L. acidophilus*. According to M.P.E.P. § 2144.06:

“It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.”

Since Hastings et al. already adds a probiotic blend to their composition it would be *prima facie* obvious to add other probiotic organisms to their invention. Therefore claims 4-10 and 20-22 are *prima facie* obvious over Hastings et al. in view of Hermann et al.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings et al. and Hermann et al. as applied to the rejections of claims 4-10 and 20-22 above and in further view of Reddy et al. (U.S. Patent # 6,080,401).

These claims further limit the composition of claim 4 by including turmeric rhizome (*curcuma longa*) as the nutritive agent.

As mentioned in the reference above, Hastings et al. in view of Hermann et al. teach a composition that comprises at least one live probiotic organism, R-lipoic acid

Art Unit: 1651

and a nutritive agent. However these two references do not specifically teach the addition of *curcuma longa* to their composition. This is taught by Reddy et al.

Reddy et al. teach a composition that, like Hastings et al., includes a probiotic blend of *Bifidobacterium* and *Lactobacillus* (Col 9, lines 33-44) to assist in weight loss and dieting (col 4, line 12), which is the same reason Hastings et al. Reddy et al. also adds *Curcuma longa* to the composition (col 8, line 5) as a hepatic stimulant. It would have been obvious to someone skilled in the art to add *Curcuma longa* to the composition of Hastings et al. since both inventions share a common goal for a composition to assist in a diet and also share common materials such as a probiotic blend (see M.P.E.P. § 2144.06).

While the art above teaches the components of the composition of claim 4 they do not teach the amounts limited by claim 12. However, M.P.E.P. § 2144.05 II states:

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

Absent any teaching of criticality by the applicant concerning the amounts listed in claim 12 for the composition of claim 4, it would be *prima facie* obvious that one of ordinary skill in the art would recognize that the amounts listed in claim 12 are result effective variables whose ratio and concentration are a matter of routine optimization.

Therefore claims 11 and 12 are *prima facia* obvious over Hastings et al. and Hermann et al. in view of Reddy et al.

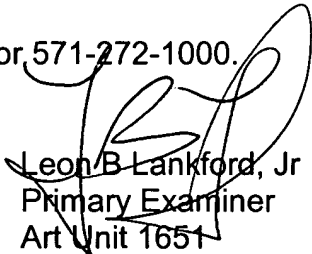
In summary no claims, as written, are allowed for this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached on 8:00 to 17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651


Leon B. Lankford, Jr.
Primary Examiner
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